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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NGUYEN, QUANG	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/672,484	CONTRERAS ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 35-89* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1, 35-89* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1 and 35-89 are pending in the present application, and they are subjected to the following restrictions.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group restriction

I. Claims 1, 35-65, 69-73, drawn to a vector capable of expressing an α-1,2-mannosidase; a vector capable of expressing a glucosidase II; a vector for disrupting the OCH1 gene in a methylotrophic yeast strain; a genetically engineered strain of a methylotrophic yeast transformed with at least one of these vectors; a method of reducing glycosylation on proteins produced by the same genetically engineered strain of a methylotrophic yeast; and a kit comprising at least one of these same vectors, classified in class 435, subclasses 320.1; 483.

II. Claims 66-68, drawn to a glycoprotein produced by the present invention, classified in class 530, subclass 350.

III. Claims 74-88, drawn to a method of for producing in methylotrophic yeast, glycoproteins having carbohydrate structures similar to those produced by human cells by introducing into a methylotrophic yeast strain at least one enzyme involved in production into the yeast strain at least one enzyme for production of $Man_5GlcNAc_2$, classified in class 424, subclass 94.1.

IV. Claim 89, drawn to a method of for producing in methylotrophic yeast, glycoproteins having carbohydrate structures similar to those produced by human cells by providing a methylotrophic yeast strain which does not express at least one enzyme involved in production of high mannose structures, classified in class 435, subclass 254.1.

The above inventions are distinct, each from the others because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case a glycoprotein of Invention II can be made in cultured human cells.

Inventions I and Inventions III-IV are distinct methods having different starting materials, and therefore they would require different technical considerations for achieving the desired end-results. For example, none of the methods of Inventions III-IV require any one of the vectors in Invention I. Please note that the method of Invention III requires the introduction of at least one enzyme for production of $Man_5GlcNAc_2$, whereas the method of Group IV does not require the use of any vector nor any enzyme, simply providing a methylotrophic yeast strain which does not express at least one enzyme involved in production of high mannose structures.

Inventions II and III-IV are not related to each other. This is because the glycoprotein of Invention II is not required to be produced by any of the methods of Inventions III-IV.

Inventions III and IV are distinct methods one from the other for the reasons already set forth above.

Because these inventions are distinct for the reasons given above, and separate search requirements in both patent and non-patent literature searches for the features characterized by each of the distinct invention, it would be unduly burdensome for the examiner **to search and/or consider the patentability of all the inventions** in a single application, restriction for examination purpose as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by

a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Species restriction

A. Should Applicants elect Group I, this application contains claims directed to the following patentably distinct species of α-1,2-mannosidase in the claimed invention:

A single specifically named α-1,2-mannosidase recited in the Markush group of claim 38.

The species are independent or distinct because each α-1,2-mannosidase from the different sources is different in the primary structure one from the others.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1,35 and 38 are generic.

Additionally, this application contains claims directed to the following patentably distinct species of a promoter in the claimed invention:

A single specifically named promoter recited in the Markush group of claim 40 or claim 46.

The species are independent or distinct because each promoter is distinct structurally and biochemically one from the others.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 35, 40, 41 and 46 are generic.

Additionally, this application contains claims directed to the following patentably distinct species of a genetically engineered methylotrophic yeast strain in the claimed invention:

A single specifically named genetically engineered methylotrophic yeast containing a single vector OR a single specific combination of vectors of claims 35, 41 or 47.

The species are independent or distinct because each genetically engineered methylotrophic yeast is distinct structurally one from the others as well as having different properties.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 48-49 are generic.

Additionally, this application contains claims directed to the following patentably distinct species of a method of reducing glycosylation on proteins or of a heterologous glycoprotein produced from a methylotrophic yeast in the claimed invention:

A single specifically named method requiring transforming the yeast with a single vector OR a single specific combination of vectors of claims 35, 41 or 47.

The species are independent or distinct because each method has different starting materials one from the others, for example whether the method involves the transformation of a yeast with a vector of claim 35, or a vector of claim 47, or with both vectors of claim 35 and 47 or with all the vectors of claims 35, 41 and 47, for examples.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 56-57 and 60-61 are generic.

Additionally, this application contains claims directed to the following patentably distinct species of a kit in the claimed invention:

A single specifically named kit containing a single vector OR a single specific combination of vectors of claims 35, 41 or 47.

The species are independent or distinct because each kit has a different component one from the others.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 69-73 are generic.

B. Should Applicants elect the invention of Group III, this application contains claims directed to the following patentably distinct species of a methylotrophic yeast in the claimed invention:

A single specifically named methylotrophic yeast recited in the Markush group of claim 85.

The species are independent or distinct because each of these methylotrophic yeasts is different structurally and biochemically one from the others.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 74, 84-85 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Dave Nguyen, may be reached at (571) 272-0731.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.